REMARKS

Election/Restriction

Applicant appreciates the Examiner's acknowledgement of Applicant's election with traverse of Group 2 in the reply filed on 2/5/09. Applicant also appreciates the Examiner's acknowledgement of Applicant's timely filing of this election.

Priority

Applicant appreciates the Examiner's acknowledgement that a proper priority claim was made in the first line of the specification. Applicant additionally appreciates the Examiner's acknowledgement that provisional application 60/415,847 supports the claims of the instant application and that claims 1,2,4-9, 11-19, 21, 23-28 and 30 are entitled to an effective filing date of 10/3/02.

Information Disclosure Statement

Applicant appreciates the Examiner's acknowledgement that the information disclosure statements filed on 4/10/06 and 4/26/07 are both in compliance with the provisions of 37 C.F.R. 1.97.

Claim Objections

The Examiner has objected to claims 5 and 19 under 37 C.F.R. 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Solely to advance prosecution and without prejudice or disclaimer of the subject matter therein, Applicant cancels both such claims.

Rejection of Claims 1, 2, 4-9, 11-19, 21, 23-28 and 30 under 35 U.S.C. 112, first paragraph

The Examiner has rejected claims 1, 2, 4-9, 11-19, 21, 23-28 and 30 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Specifically, the Examiner claims the specification fails to describe a limiting definition of "oxytocin analog."

Initially, Applicant notes that the specification defines an analog as a, "molecule that demonstrates bioactivity less than, similar to or greater than oxytocin itself," the bioactivity of which is known to those of skill in the art. (Specification, p. 3, paragraph [0023]) Additionally, "such molecule may be a synthetic analog, fragment of oxytocin, pharmaceutically acceptable salt of oxytocin capable of oxytocin-like activity." (*id.*) Particular examples of analogs are also given in paragraphs [0027] to [0030]. Applicant is entitled to rely upon the ordinary and common usage of terms well known to those of skill in the art. Applicant respectfully argues that the term "analog" is commonly understood by those of skill in the art and, as such, the term "analog" has a definite meaning to one of skill in the art and meets the requirements of 35 U.S.C. 112, second paragraph.

Applicant also directs the Examiner's attention to cases that established the groundwork for the *In re Wands* test, such as *In re Angstadt*, 537 F.2d 498, 190 USPQ 214 (CCPA 1976). In that case the inventors appealed a board decision holding undue experimentation would be required to determine which of thousands of possible combinations would work to produce hydroperoxides in their claimed catalytic process. First, the court determined that the claimed process was an "unpredictable" art. The dissent argued that the disclosure must provide "guidance which will enable one skilled in the art to determine, *with reasonable certainty before performing the reaction*, whether the claimed product will be obtained" (emphasis in original) *In re Angstadt*, 190 USPQ at 222. The majority rejected this approach, arguing that under the dissent's standard, "all 'experimentation' is 'undue' since the term 'experimentation' implies that the success of the particular activity is *uncertain*. Such a proposition is contrary to the basic policy of the Patent Act", *In re Angstadt*, 190 USPQ at 219. The majority continued, "What the

dissent seems to be obsessed with is the thought of catalysts which *won't* work to produce the intended result. Without undue experimentation or effort or expense the combinations which do not work will readily be discovered and, of course, nobody will use them and the claims do not cover them." (emphasis in original), *In re Angstadt*, 190 USPQ at 219.

The Court of Appeals for the Federal Circuit (CAFC) has upheld the holding of *In re Angstadt* on many occasions post establishing the *In re Wands* test, including in biotechnology cases. For example, in *Amgen Inc. v. Chugai Pharmaceutical Co.*, 18 USPQ 1016, 1027 (CAFC 1991) the court cited *In re Angstadt* as standing for the proposition that "it is not necessary that a patent applicant test all the embodiments of his invention".

Applying the reasoning of the majority of *In re Angstadt* to the present application, Applicant respectfully argues that 35 U.S.C. 112 does not require the specification to set forth teachings in order to guide one of skill in the art on how to practice all possible embodiments or to predict which compounds will work. Rather, what is required is that one of skill in the art must have sufficient guidance to be able to determine whether or not a given compound falls within the scope of the claim. That is, Applicant asserts that given the teachings of the present application, determining whether a given compound falls within the claims is clearly specifically taught by the present invention or a matter of routine screening. See *In re Wands* 8 USPQ2d 1400, 1404 in which the court held routine screening does not constitute undue experimentation.

In light of the above, Applicant respectfully requests withdrawal of the rejection of claims 1, 2, 4-9, 11-19, 21, 23-28 and 30 under 35 U.S.C. 112, first paragraph.

Rejection of Claims 18 and 27 under 35 U.S.C. 112, second paragraph

The Examiner has rejected claims 18 and 27 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner contends the term,"10 μg/ml" is a relative term that renders the claims indefinite as it is recited as a "therapeutically effective amount."

Solely to advance prosecution and without disclaimer of the subject matter therein, Applicant has amended the claim to read that, "10 units/ml oxytocin dissolved into 1000 mL normal saline, administered at a rate of 10 milliunits/minute or 6 units/hour." A paragraph replacement will be included in a future response if this language is acceptable.

In light of this amendment, Applicant respectfully requests withdrawal of the rejection of record for claims 18 and 27.

Rejection of claims 1, 5, 6, 12, 15, 19, 23 and 28 under 35 U.S.C. 102

The Examiner has rejected claims 1, 5, 6, 12, 15, 19, 23 and 28 under 35 U.S.C. 102(b) as anticipated by Knauf (DE 4429880, published 3/31/1994).

The Examiner appears to be mischaracterizing the reference as it is an extremely brief description of the personal beliefs of the inventor. Specifically, the inventor discloses that the lack of love and tenderness in childhood results in a lack of oxytocin, vasopressin and endorphins in an adult. This false belief of the inventor has absolutely no supporting experimental results and/or scientific data of any kind anywhere in the referemce. Additionally, the inventor makes a variety of false statements throughout the patent application that renders all statements within it suspect. Particular examples include the following:

- Love and tenderness are the prerequisite for the release of the 3 neurohormones oxytocin, vasopressin and endorphins into the blood. ... Proline is responsible for the cyclic release of these hormones. (p. 2, lines 6-7 and 8 of translation)

- If the mother is not in a position to give the child love and tenderness, if she dies at a very early stage or if she mistreats her child by physical or psychological abuse, oxytocin, vasopressin and endorphins may be deficient. (p. 2, lines 11-13)

- Affection from other people hurts them and they find it unpleasant. Later in life they are incapable of giving love and tenderness to their wives, husbands and children. This can be attributed primarily to the lack of oxytocin and endorphins. (p. 2-3, lines 30-31 and 1-2)

- As a result of the deficiency of the neurohormones in the blood, there is an increased secretion of gonadotrophic hormones in the anterior pituitary which increases the synthesis of testosterone and thus causes abnormally high sexuality which together with the negative experiences in childhood casues such people to be sexually driven murderers and sex offenders. (p. 3, lines 4-8).

- Autistic children and adults: The reason for this is again a lack of love and tenderness in childhood and these people have been hit a great deal. They are mostly people with no oxytocin and endorphins in the blood. These people find all touching repellent. They do not like to be touched (six) and scarcely touch other people. If they are touched, this is unplkeasant to them an dmay even cause them pain, which can be put down to the absence of endorphins, in particular. Such people are particularly hypersensitive to pain. (p. 4, lines 12-17).

These are but a few examples of the false statements made by the inventor of this reference and numerous additional examples can be found throughout it. As such, this reference does not appear to meet the requirements for this rejection to be valid as the article does not provide an enabling disclosure for treatment of autism with oxytocin. At most, it appears to be a

suggestion to try replacing oxytocin, vasopressin and endorphins to treat sexually driven murderers, homosexuals, those incapable of demonstrating love and affection and the like. With the plethora of psychological, physiological, behavioral and criminal problems being attributed a lack of oxytocin, vasopressin and endorphins in the reference, it does not at all include an enabling disclosure to allow one skilled in the art to practice the methods of the present invention.

Independent claim 1 is directed to a treatment method for an individual demonstrating behavioral characteristics associated with autism whereby the individual is given a therapeutically effective amount of oxytocin. The subject reference does not address the behavioral characteristics associated with autism and, in contrast, is directed to treating an enormous number of maladies and criminal behaviors with an unspecified regime of replacing oxytocin, vasopressin and endorphins. Additionally, one skilled in the art would in no way take this article seriously as it contains a multitude of false statements rendering any disclosure contained within it suspect.

In light of the above, Applicant respectfully requests withdrawal of the rejection of claims 1, 5, 6, 12, 15, 19, 23 and 28 under 35 U.S.C. 102(b).

Rejection of claims 1, 2,4-9, 11,12,15-19 and 23-28 are rejected under 35 U.S.C. 102(e)

The Examiner has rejected claims 1, 2, 4-9, 11, 12, 15-19 and 23-28 under 35 U.S.C. 102(e) as being anticipated by Quay (U.S. Patent No. 6,894,026) for the reasons of record. Applicant respectfully traverses this rejection.

Initially, Applicant respectfully submits that the Examiner mischaracterizes the teachings of Quay. The Examiner states that, "Quay teaches methods of administering a therapeutically effective amount of the oxytocin analog carbetocin, and/or other long-acting oxytocin analogs, either alone or coordinately with an antidepressant such as a selective serotonin receptor antagonist (SSRI), to prevent, treat or alleviate the symptoms of autism (col. 5, lines 39-49 and col 6, lines 24-28. In actuality, that is not true. Lines 39-49 state, "[t]he methods of the invention involve administering a therapeutically effective amount of carbetocin and/or other

long-acting oxytocin analogues to a patient suffering from breast cancer, or a psychiatric disorder, or presenting with an elevated risk for developing such disease or disorder." (emphasis added) Additionally, lines 24-38 in column 6 state, "[i]n other aspects of the invention, carbetocin and/or another long-acting oxytocin analogue is administered according to the foregoing methods in a coordinate treatment or prophylaxis protocol with an antidepressant, such as a selective serotonin reuptake inhibitor (SSRI) or serotonin reuptake inhibitor (SRI)."

As evidenced above, neither quotation relied on by the Examiner includes anything but a broad reference to psychiatric disorders and neither the Specification or the Examples provide any instruction whatsoever as to how a clinician would treat a patient with a non-psychiatric disorder, like autism. Autism, in contrast to a psychiatric disorder, is a neurodevelopmental disorder and, due to this distinction, is not eligible for insurance reimbursement as a psychiatric disorder anywhere in the United States. As such, a broad statement to treatment of psychiatric disorders does not teach one skilled in the art how to treat an autistic patient as autism is not a psychiatric disorder.

As such, Applicant respectfully requests that the Examiner withdraw the rejections against claims 1, 2, 4-9, 11, 12, 15-19 and 23-28 under 35 U.S.C. 103(a).

Rejection of claims 13 and 14 under 35 U.S.C. 103(a)

The Examiner has rejected claims 13 and 14 under 35 U.S.C. 103(a) as being unpatentable over Knauf in view of Quay for the reasons of record. Applicant respectfully traverses this rejection.

As stated above, Applicant would like to point out that to establish a prima facie case of obviousness, it must be shown that each and every one of the claim limitations was suggested or taught by the prior art beieng relied upon. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1974). When an independent claim is deemed nonobvious under 35 U.S.C. 103 then all claims depending therefrom are nonobvious as well. *In re Fine*, 837 F.2d 1071, 5 USPQ 2d 1596 (Fed.

Cir. 1988).

Applicant respectfully asserts the Examiner has not met this burden. As explained under the 102(a) rejection above, Knauf does not describe a treatment method for an individual demonstrating behavioral characteristics associated with autism whereby the individual is given a therapeutically effective amount of oxytocin. Knauf also does not address the behavioral characteristics associated with autism and, in contrast, is directed to treating an enormous number of maladies and criminal behaviors with an unspecified regime of replacing oxytocin, vasopressin and endorphins. Additionally, one skilled in the art would in no way take this article seriously as it contains a multitude of false statements rendering any disclosure contained within it suspect. Applicant respectfully submits that Quay does not disclose a method of treating autism. As described above, Quay discloses a method of treating a patient suffering from breast cancer, or a psychiatric disorder, which has no relevance to autism as it is a neurodevelopmental disorder.

Accordingly, the Examiner has not overcome the aforementioned burden since each and every one of the claim limitations of the instant invention were not taught or suggested by Knauf or Quay, when viewed individually or in combination with one another.

As such, Applicant respectfully requests that the Examiner withdraw the rejections against claims 13 and 14 under 35 U.S.C. 103(a).

Rejection of claims 21 and 30 under 35 U.S.C. 103(a)

The Examiner has rejected claims 21 and 30 under 35 U.S.C. 103(a) as being unpatentable over Knauf in view of Begley. Applicant respectfully traverses this rejection.

As explained under both the 102(a) and 103(a) rejection above, Knauf does not describe a treatment method for an individual demonstrating behavioral characteristics associated with autism whereby the individual is given a therapeutically effective amount of oxytocin. Knauf also does not address the behavioral characteristics associated with autism and, in contrast, is directed to treating an enormous number of maladies and criminal behaviors with an unspecified regime of replacing oxytocin, vasopressin and endorphins. Additionally, one skilled in the art

would in no way take this article seriously as it contains a multitude of false statements rendering any disclosure contained within it suspect.

Applicant also respectfully disagrees with the Examiner's statement that: "it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to be motivated to use oxytocin to treat symptoms of autism, as taught by Knauf and Begley et al." In this regard, Applicant respectfully directs the Examiner's attention again to page 1, paragraph [0011] of the present application which reads:

> "The reduction of the severity of behaviors associated with autism upon administration of oxytocin appears unexpected in light of earlier work, which apparently indicated that, while lower levels of oxytocin were present in autistic children when compared to normal patients, among the autistic children, higher levels of oxytocin were correlated with lower interaction and daily living skills, as well as with an overall greater deficit in social awareness." (emphasis added)

The statement above from the present application is in direct contrast with the Examiner's belief that the one skilled in the art at the time the invention was made would have been motivated to use oxytocin to treat symptoms of autism.

As such, Applicant respectfully requests that the Examiner withdraw the rejections against claims 21 and 30 under 35 U.S.C. 103(a).

Concluding Remarks

In view of the foregoing remarks, Applicant respectfully requests reconsideration and examination as to the merits of the application. If the Examiner notes any further matters which would be expedited by a telephonic interview, she is requested to contact Dr. Jennifer M. McCallum at the telephone number listed below.

Respectfully Submitted,

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Date

Jennifer M. McCallum, Ph.D., Esq.
Reg. No. 62,492
The McCallum Law Firm, PC
685 Briggs Street
P.O. Box 929
Erie, CO 80516
Telephone: (303) 828-0655
Fax: (303) 828-2938
e-mail: administration@mccallumlaw.net